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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/517,637	04/11/2005	Jorg Peter	085449-0157	3124

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FOLEY AND LARDNER LLP  
SUITE 500  
3000 K STREET NW  
WASHINGTON, DC 20007

EXAMINER
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CHAO, ELMER M

ART UNIT	PAPER NUMBER
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3737

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08/30/2010

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/517,637	<b>Applicant(s)</b> PETER, JORG	
	<b>Examiner</b> ELMER CHAO	<b>Art Unit</b> 3737	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 01 July 2010.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 22-43 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 22-43 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                    | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)         | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____   | 6) <input type="checkbox"/> Other: _____                          |

## DETAILED ACTION

### ***Continued Examination Under 37 CFR 1.114***

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 7/1/2010 has been entered.

### ***Claim Objections***

2. **Claim 29 and all its dependents** are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Since apparatus claim 29 could be infringed on by an apparatus that does not necessarily involve the method steps of claim 22, the claim fails to satisfy the infringement test. See MPEP § 608.01(n), "Infringement Test" for dependent claims. The test for a proper dependent claim is whether the dependent claim includes every limitation of the parent claim. The test is not whether the claims differ in scope. A proper dependent claim shall not conceivably be infringed by anything which would not also infringe the basic claim.

***Double Patenting***

3. Applicant is advised that should claim 42 be found allowable, claim 23 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

***Claim Rejections - 35 USC § 103***

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. **Claims 22 and 28** are rejected under 35 U.S.C. 103(a) as being unpatentable over Combs et al. (U.S. 6,280,703 B1) in view of Nelson et al. (U.S. 4,969,175). Combs et al. teach an imaging method, comprising: simultaneously (claim 7) or alternately (claim 8) determining in vivo distributions of bioluminescent and/or fluorescent markers and radioactive markers (claim 1), wherein the distribution of the bioluminescent and/or fluorescent markers is determined by separate detection of photons having a first average energy, which are emitted by the bioluminescent and/or fluorescent markers (claim 1, part i), by at least one first detector and wherein the distribution of the radioactive markers is determined by separate detection of photons having a second

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average energy, which are emitted by the radioactive markers (claim 1, part ii), by at least one second detector, wherein the at least one first detector and the at least one second detector are fixedly and rigidly arranged in a specific spatial arrangement relative to each other (some determined spatial arrangement would be necessary, especially in the case of simultaneous detection).

Combs et al. teach the limitations as discussed above but fail to explicitly teach the detectors placed at identical projection angles. However, in the field of multiple energy x-ray imaging, Nelson et al. teach imaging at two different energy levels at the same projection angle (col. 4, lines 38-42). Therefore, it would have been obvious to a person of ordinary skill in the art at the time of the invention to perform both determine the distributions of the markers at the same projection angle in order to properly compare the detected energies relative to the part being imaged (for motivation see col. 4, lines 38-42).

6. **Claims 23, 24, 43, and 44** are rejected under 35 U.S.C. 103(a) as being unpatentable over Combs et al. in view of Nelson et al., and further in view of Rubinstein et al. (U.S. 6,757,554 B2). Combs et al. and Nelson et al. teach the limitations as discussed above but fail to explicitly teach a layer used to transmit or reflect photons according to their energy level. However, in the field of fluorescent imaging, Rubinstein et al. teach providing a filter (col. 8, lines 43-50). Therefore, it would have been obvious to a person of ordinary skill in the art at the time of the invention to provide a layer for each the detectors as it is functionally equivalent to a filter in order to minimize background emissions and only allow the intended range of

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emissions energies to pass (for motivation see col. 8, lines 45-50). Furthermore, one of ordinary skill in the art would understand that the filter is an obvious solution for the selective separation of the different photon energies to their respective detectors.

7. **Claim 25** is rejected under 35 U.S.C. 103(a) as being unpatentable over Combs et al. in view of Nelson et al. as applied to claim 22 above, and further in view of Bryan et al. (U.S. 6,232,107 B1). Combs et al. and Nelson et al. teach the limitations as discussed above but fail to explicitly teach using green fluorescent proteins. However, in the field of using in-vivo markers, Bryan et al. teach using green fluorescent proteins (Para [0025]). Therefore, it would have been obvious to a person of ordinary skill in the art at the time of the invention to include using fluorescent proteins in order follow the migration and colonization progresses of tumor cells (for motivation see Para [0025] second and third sentences).

8. **Claim 26** is rejected under 35 U.S.C. 103(a) as being unpatentable over Combs et al. in view of Nelson et al. as applied to claim 22 above, and further in view of Turner (U.S. 2003/0101466 A1). Combs et al. and Nelson et al. teach the limitations as discussed above but fail to explicitly teach detecting Indium-111 using SPECT. However, in the field of using radioactive markers, Turner teaches using SPECT to detect Indium-111 among other listed radioactive markers (Para [0027], first sentence, second to last sentence). Therefore, it would have been obvious to a person of ordinary skill in the art at the time of the invention to use SPECT imaging to detect Indium-111 in order to detect cancer cells (for motivation see abstract).

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9. **Claims 27** is rejected under 35 U.S.C. 103(a) as being unpatentable over Combs et al. in view of Nelson et al., further in view of Turner as applied to claim 22 above, and further in view of Voirin et al. (U.S. 6,312,961 B1). Combs et al., Nelson et al., and Turner teach the limitations as discussed above but fail to explicitly teach the fluorescent markers being detected by a CCD camera. However, in the field of fluorescent imaging, Voirin et al. teach a CCD array to detect fluorescent emissions (col. 6, lines 10-39). Therefore, it would have been obvious to a person of ordinary skill in the art at the time of the invention to use a CCD array to detect fluorescent emissions in order to achieve a large enough number of pixels (for motivation see col. 6, lines 24-29).

10. **Claims 29 and 30** are rejected under 35 U.S.C. 103(a) as being unpatentable over Combs et al. in view of Nelson et al., further in view of Turner, further in view of Voirin et al., and further in view of Rubinstein et al. (U.S. 6,757,554 B2).

Regarding **claims 29 and 30**, Combs et al., Nelson et al., Turner, and Voirin et al. teach the limitations as discussed above but fail to explicitly teach a layer used to transmit or reflect photons according to their energy level. However, in the field of fluorescent imaging, Rubinstein et al. teach providing a filter (col. 8, lines 43-50). Therefore, it would have been obvious to a person of ordinary skill in the art at the time of the invention to provide a layer for each the detectors as it is functionally equivalent to a filter in order to minimize background emissions and only allow the intended range of emissions energies to pass (for motivation see col. 8, lines 45-50).

11. **Claims 31-34 and 36-41** are rejected under 35 U.S.C. 103(a) as being unpatentable over Combs et al. in view of Nelson et al., further in view of Turner, further

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in view of Voirin et al., further in view of Rubinstein et al. as applied to claim 29 above, and further in view of Rabito et al. (U.S. 5,647,363). Combs et al., Nelson et al., Turner, Voirin et al., and Rubinstein et al. teach the limitations as discussed above but fail to explicitly teach the different configurations and arrangements of the SPECT and CCD cameras. However, in the same field of endeavor, Rabito et al. teach a configuration of four detectors (see fig. 8), wherein the detectors can be radioactive and fluorescent detectors (col. 3, lines 24-37). Therefore, it would have been obvious to a person of ordinary skill in the art at the time of the invention to include using different configurations of the SPECT and CCD cameras as a matter of design choice which depends on the area being imaged or the information being acquired.

12. **Claim 35** is rejected under 35 U.S.C. 103(a) as being unpatentable over Combs et al. in view of Nelson et al., further in view of Turner, further in view of Voirin et al., further in view of Rubinstein et al. as applied to claim 29 above, further in view of Rabito et al. as applied to claim 34 above, and further in view of Matsuzaki et al. (U.S. 2002/0042566 A1). Combs et al., Nelson et al., Turner, Voirin et al., and Rubinstein et al., and Rabito et al. teach the limitations as discussed above but fail to explicitly teach using a position sensor. However, in the field of medical imaging, Matsuzaki et al. teach using a position sensor (Para [0096]). Therefore, it would have been obvious to a person of ordinary skill in the art at the time of the invention to modify to include a position sensor in order to track a subject (for motivation see Para [0096]).



***Response to Arguments***

13. Applicant's arguments filed 9/24/2009 have been fully considered but they are not persuasive.

Applicants' arguments with respect to the 112 rejection (page 9, Arguments) are noted and Examiner has removed the rejection.

Applicants argue that Combs et al. do not teach "imaging" (page 10, second to last paragraph - page 11, first paragraph; page 14, first paragraph; page 15, first paragraph; page 16, first paragraph; page 17, first paragraph; page 18, first paragraph; page 19, first paragraph; Arguments). In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., "imaging") are not positively recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). Examiner notes that nowhere in independent claims 22 and 28 is there a positive recitation of an imaging step. Applicants are implying a narrower interpretation of the word "imaging", which does not even show up in the claim except for the preamble. Even if the step of imaging is recited in the body of the claim language, the claim still lacks the step of producing an image from the detected signals. Applicants' own claims do not recite anything other than detecting signals. Therefore, there is no basis for Applicants to argue that the "imaging method" recited by the claims should be read to mean something narrower than the mere detection of signals. In the field of medical imaging, reciting the step of

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"imaging" does not necessarily involve the processing of raw image data into an actual tangible image. Take for example the hypothetical step of "imaging a portion of the human body using an MRI device", which only implies that raw data is collected by an MRI device, but not necessarily formulating a visible image of the body, and it does not specify whether the raw data that is collected by is done over a 2D slice, 3D volume, or 1D point. Applicants' recitation of "imaging" in claims 22 and 28 is even broader than this example and therefore Applicants clearly have no basis for using this recitation to argue over Combs.

Applicants argue that "As Combs does not provide a method of imaging in any form, modification of this method with that of Nelson would not lead to the presently claimed invention." (page 11, second paragraph, Arguments). Examiner notes that whether or not Comb's discloses the word "imaging" is irrelevant to the combination of Nelson and Combs. Merely pointing out that Nelson is drawn to a method of imaging and Combs does not disclose the word "imaging" does not render the combination/modification inoperable by at least the rationale provided above regarding the interpretation of "imaging". Furthermore, it has been held that a prior art reference must either be in the field of applicant's endeavor or, if not, then be reasonably pertinent to the particular problem with which the applicant was concerned, in order to be relied upon as a basis for rejection of the claimed invention. See *In re Oetiker*, 977 F.2d 1443, 24 USPQ2d 1443 (Fed. Cir. 1992). In this case, both Combs and Nelson on related because Nelson is pertinent to the problem of detection radiation at two different energy levels (col. 4, lines 38-42, Nelson).

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Regarding claims 23 and 24, Applicants argue that Rubinstein's filter is utilized to filter out specific wavelengths of light and do not explicitly "allow for separate reflection or transmission of photons of the bioluminescent and/or fluorescent markers having a first average energy and photons of the radioactive markers having a second average energy" (page 12, last paragraph - page 13, first paragraph, Arguments). Examiner notes that Combs already teaches the simultaneous detection of the bioluminescent and fluorescent markers. Combs do not explicitly teach that a "layer" (i.e. filter) is used to separate the signals to the detectors. In view of Rubinstein et al.'s teaching as explained in the above office action and in the previous office action, one of ordinary skill in the art would understand that the filter is an obvious solution for the selective separation of the different photon energies to their respective detectors. In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). Applicants also argue that "since only a concentration is to be measured in Rubinstein, only a single light intensity is provided by the photodetector" (page 13, second paragraph, Arguments). Examiner notes that this is irrelevant in view of the fact that Rubinstein still teaches the use of a filter to separate the photons of a given energy and would still be applicable to other light detection applications such as imaging.

***Conclusion***

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to ELMER CHAO whose telephone number is (571)272-0674. The examiner can normally be reached on Mon-Thurs 11am-9pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Casler can be reached on (571)272-4956. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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